INTERNATIONAL STANDARD

ISO 5367

Fourth edition
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Breathing tubes intended for use with anaesthetic apparatus and ventilators

Tuyaux de ventilation destinés à être utilisés avec des appareils d'anesthésie et des ventilateurs

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 5367 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This fourth edition cancels and replaces the third edition (ISO 5367:1991), which has been technically revised. This edition differs from the previous edition primarily in that all sizes of breathing tubes are included and that each tube is required to be marked with the rated flow that the manufacturer claims can be achieved without exceeding specified limits for resistance.

Annexes A, B, C, D, E and F form a normative part of this International Standard. Annex G is for information only.

Introduction

This International Standard is one of a series dealing with anaesthetic and respiratory equipment. It is primarily concerned with basic requirements for breathing tubes. Breathing tubes are characterized by the rated flow that a manufacturer claims can be achieved without exceeding specified limits for resistance. The requirements also include means of connection and several test methods, some of which have not been included in earlier editions of this International Standard.

This International Standard includes requirements for both single-use and re-usable breathing tubes. Re-usable breathing tubes are intended to comply with the requirements of this International Standard for the recommended product life.

Certain tests are performed under constant pressure to simplify the test methodology. It is recognized that this does not reflect clinical use, when pressure is (only) intermittent and peak pressures occur for short periods. The limits set in the test methods take this into account. Whilst such test methods do not address product variability, the limits set also take this into account.

Recommendations for materials and design are given in annex G.

Breathing tubes intended for use with anaesthetic apparatus and ventilators

1 Scope

This International Standard specifies basic requirements for antistatic and non-antistatic breathing tubes and breathing tubing supplied to be cut to length, intended for use with anaesthetic apparatus and ventilators, humidifiers and nebulizers. It also applies to breathing tubes and Y-pieces supplied already assembled and to those supplied as components and assembled in accordance with the manufacturers' instructions.

Provision is made for breathing tubes having ends incorporating adaptors with conical connectors (assembled ends) or with plain ends (either cylindrical or tapered).

Breathing tubes for special purposes, such as those used with ventilators having special compliance requirements and coaxial lumen tubes, are outside the scope of this International Standard.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 468, *Surface roughness — Parameters, their values and general rules for specifying requirements.*

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing.*

ISO 11607, *Packaging for terminally sterilized medical devices.*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

EN 556:1994, *Sterilization of medical devices — Requirements for medical devices to be labelled "STERILE".*

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply.

3.1
APL valve
adjustable pressure-limiting valve
pop-off valve
pressure-limiting valve which releases gas over an adjustable range of pressures

[ISO 4135]

3.2
breathing tube
non-rigid tube used to convey gases and/or vapours between components of a breathing system

[ISO 4135]

3.3
adaptor
specialized connector to establish functional continuity between otherwise disparate or incompatible components, one end of which is intended to be inserted into the end of a breathing tube, the other end having a conical connector complying with ISO 5356-1

3.4
assembled end
end of a breathing tube incorporating an adaptor

3.5
plain end
end of a breathing tube designed to fit directly over a male conical connector complying with ISO 5356-1

3.6
patient end
that end of the breathing tube which is intended to be connected to the Y-piece or other appropriate component near the patient

3.7
machine end
that end of the breathing tube which is intended to be connected to the anaesthetic workstation, ventilator or other breathing attachment furthest from the patient

3.8
anti-static
property of breathing tubes and any integrally attached components with electrical conductivity satisfying specified limits under the test conditions

3.9
compliance
volume added per unit pressure increase when gas is added to an enclosed space, expressed at the temperature and humidity of that enclosed space and at an ambient atmospheric pressure

[ISO 4135]

3.10
patient connection port
that opening at the patient end of a breathing system intended for connection of a device such as a tracheal or tracheostomy tube connector, a face mask, a laryngeal mask airway or a cuffed oropharyngeal airway

[ISO 4135]

3.11
3-way breathing system connector
Y-piece
tubular connector with three ports, one of which is a patient connection port

[ISO 4135]

3.12
swivel 3-way breathing connector
swivel Y-piece
specialized three-way connector which allows variation in the position of its three ports relative to each other

[ISO 4135]

3.13
rated flow
flow that the manufacturer claims results in an increase in pressure of not more than that specified in 4.5.1 or 4.5.2, as appropriate

4 General requirements

4.1 Re-usable breathing tubes

Re-usable breathing tubes shall comply with the requirements of this International Standard throughout the recommended product life as specified in 8.2.

4.2 Materials

Breathing tubes, in their ready-for-use state after any preparation recommended by the manufacturer, shall satisfy appropriate biological safety testing, in accordance with ISO 10993-1.

NOTE Recommendations for materials are given in annex G.

4.3 Design

Breathing tubes, whether of corrugated construction or otherwise, shall have plain ends (cylindrical or tapered) and/or assembled ends incorporating 22 mm or 15 mm conical connectors complying with ISO 5356-1.

NOTE 1 A loop for suspending the tube may be provided near one of the ends.

NOTE 2 The ends of breathing tubes may be constructed to engage with the recess at the base of a 22 mm male conical connector.

NOTE 3 Recommendations for design are given in annex G.

4.4 Length

4.4.1 The length of breathing tubes shall be designated by their nominal overall length, expressed in metres, when measured in the resting condition (without being held under tension), lying on a horizontal surface. Breathing tubes intended to be extended when used shall be designated by both the unextended and extended lengths.

4.4.2 The designated length of breathing tubes provided integrally attached to a Y-piece shall include the length of the Y-piece and any assembled ends.

4.4.3 The actual length shall be within 10 % of the designated length.

4.5 Resistance to flow

4.5.1 The manufacturer shall determine the rated flow to be marked.

4.5.2 When a breathing tube supplied ready for use (with assembled ends and Y-piece, if provided) is tested in accordance with annex A using the rated flow marked by the manufacturer [see 7.2 d) and 7.3 d)], the increase in pressure shall not exceed 0,2 kPa.

4.5.3 When breathing tubing supplied to be cut to length is tested in accordance with annex A using the rated flow marked by the manufacturer [see 7.2 e) and 7.3 e)], the increase in pressure shall not exceed 0,1 kPa per metre length of tubing.

4.6 Means of connection

4.6.1 Plain ends of tubes

4.6.1.1 The axial length (l_1) of plain ends of breathing tubes [see Figure 1 a)], excluding those specified in 4.6.1.2, shall be not less than 21 mm for breathing tubes intended to engage with 22 mm male conical connectors or not less than 14 mm for breathing tubes intended to engage with 15 mm male conical connectors.

4.6.1.2 The axial length (l_2) of plain ends of breathing tubes that incorporate an internal ridge [see Figure 1 b)], intended to engage with the recess at the base of a 22 mm male conical connector as specified in ISO 5356-1, shall be not less than 26,5 mm.

4.6.1.3 When tested as described in annex B, plain ends of breathing tubes shall not become detached from the appropriate male conical connector at a force of less than 40 N.

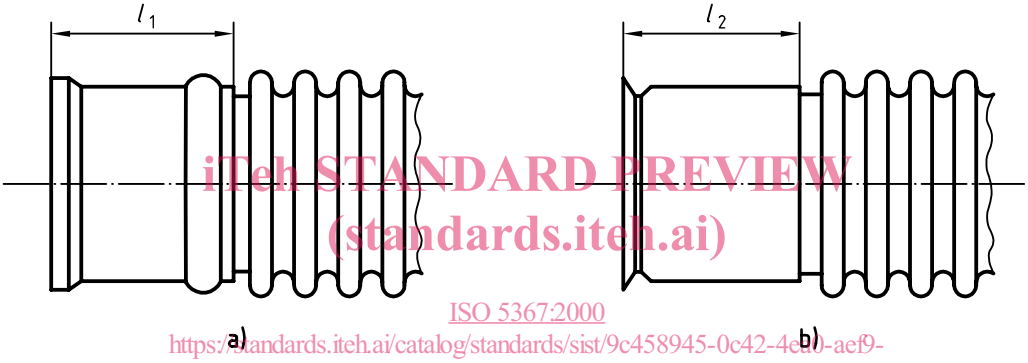

Figure 1 — Axial length of plain end of breathing tube

4.6.2 Adaptor

The end of the adaptor that is not intended for attachment to the breathing tube shall have a 22 mm or 15 mm conical connector complying with ISO 5356-1.

4.6.3 Assembled end

When tested as described in annex C, the adaptor shall not become detached from the tube at a force of less than 45 N.

NOTE For the purpose of this requirement, a Y-piece provided integrally attached to a breathing tube is regarded as an adaptor.

4.6.4 Breathing tubes integrally attached to a Y-piece

If breathing tubes are supplied in pairs integrally attached to a Y-piece, the patient connection port of that Y-piece shall be a 22 mm male/15 mm female coaxial or 15 mm female conical connector complying with ISO 5356-1.

4.7 Leakage

4.7.1 When tested in accordance with annex D, breathing tubing supplied to be cut to length shall not leak at a rate of more than 10 ml·min^{-1} per metre length of tubing.

Care should be taken when performing the test to exclude the possibility of leaking between the tubing and the apparatus.

4.7.2 When tested in accordance with annex D, single breathing tubes shall not leak at a rate of more than 25 ml·min^{-1}.

4.7.3 When tested in accordance with annex D, breathing tubes supplied in pairs integrally attached to a non-swivel Y-piece, shall not leak at a rate of more than 50 ml·min^{-1}.

4.7.4 Breathing tubes with integrally attached specialized adaptors, e.g. a swivel Y-piece, shall either:

a) not leak at a rate of more than 50 ml·min^{-1} when tested in accordance with annex D, or

b) be marked with the leakage rate determined in accordance with annex D [see 7.2 f) and 7.3 f)].

4.7.5 Breathing tubes marked in accordance with 4.7.4 b) shall have a marked leakage rate of not more than 150 ml·min^{-1}.

4.7.6 The actual leakage rate of breathing tubes marked in accordance with 4.7.4 b) shall not be more than 10 % greater than the marked leakage rate.

4.8 Increase in flow resistance with bending

When tested in accordance with annex E, the pressure at the rated flow when the breathing tube is suspended over the metal cylinder shall not exceed 150 % of the value obtained with the tube straight.

4.9 Compliance

The compliance of breathing tubes at a pressure of 6 kPa shall not exceed 10 ml·kPa^{-1} per metre length of tube when tested in accordance with annex F.

5 Prevention of electrostatic charges

5.1 Antistatic breathing tubes and any integrally attached components [see 7.2 c)] shall comply with the requirements for prevention of electrostatic charges specified in subclause 39.3 b) of IEC 60601-1:1988.

5.2 Breathing tubes coloured black shall be antistatic and comply with 5.1.

6 Requirements for breathing tubes supplied sterile

6.1 Sterility assurance

Breathing tubes supplied and marked “STERILE” shall satisfy the requirements of 4.1 of EN 556:1994.

6.2 Packaging of breathing tubes supplied sterile

6.2.1 Breathing tubes supplied and marked “STERILE” shall be contained in an individual pack.